

## REMARKS

In the Office Action, claims 30-54 are rejected under 35 U.S.C. § 103 as allegedly unpatentable over U.S. Patent No. 4,720,390 ("Bachler") in view of U.S. Patent No. 4,919,958 ("Kadan") and U.S. Patent No. 2,487,600 ("Schneiderwirth") and Bowes and Church's Food Values, pages 58 ("Food Values"). The Patent Office primarily relies on Bachler and thus relies on the remaining cited art to support the deficiencies of same.

Applicants believe that the obviousness rejection is improper and should be withdrawn. Of the pending claims at issue, claims 30, 47 and 54 are the sole independent claims. Claim 30 recites a gelled nutritional composition. The composition includes a protein source with gelled protein, a carbohydrate source, minerals, and vitamins wherein the protein source provides 10% to 25% of the energy of the composition and the carbohydrate source provides 75% to 90% of the energy of the composition.

Claim 47 recites a method of providing nutrition to a patient suffering from dysphagia. The method includes administering to the patient a gelled nutritional composition that contains a protein source with gelled whey protein, a carbohydrate source, minerals and vitamins.

Claim 54 recites a method for providing supplemental nutrition to a child. The method includes administering to the child a gelled nutritional composition that contains a protein source with gelled whey protein, a carbohydrate source, minerals and vitamins.

The gelled nutritional compositions of the present invention include four major components, namely, proteins including gelled whey protein, carbohydrates, minerals and vitamins. The nutritional product as claimed is further defined by the protein and carbohydrate content expressed as an energy content. Applicants have discovered that the gelled nutritional composition as claimed can be particularly useful as a nutrition for persons suffering from dysphagia which often occurs after medical or dental surgery, children and the like. In this regard, the claimed gelled nutritional compositions can be readily swallowed and, in addition, provide a desirable energy balance. See, Specification, p. 3, lines 11-17.

In contrast, the cited references, even if combinable, fail to disclose or suggest the claimed invention. At the outset, the primary Bachler reference is deficient with respect to the claimed invention for at least a number of reasons. For example, the Bachler reference is

deficient with respect to the energy content associated with the carbohydrate as even admitted by the Patent Office. See, Office Action, page 2.

Further, the primary focus of Bachler relates to an oil-in-water emulsion that can be utilized as a replacement of eggs, thickeners or gelling agents. See, Bachler, col. 5, lines 3-5. Clearly, the claimed invention is not directed to a substitute for a gelling agent but instead the claimed gelled nutritional compositions include such gelling agents (i.e., gelled whey protein) to provide a well-balanced nutritional product that is particularly beneficial for persons suffering from dysphagia as discussed above.

Moreover, the food compositions as disclosed in Bachler provide a high-fat content with a very low carbohydrate content. For example, Bachler provides a preparation of a jelly that includes water, one kg whey concentrate, 0.3 kg raspberry syrup and 2 kg butter. Thus, the total caloric content provided by fat for such jelly preparation can be estimated at 70% to 80%. With such a high-fat content, this type of composition is clearly inadequate for providing a well-balanced nutrition to any person, particularly persons recovering from a surgery and suffering from dysphagia in contrast to the claimed invention. Therefore, Bachler on its own is clearly distinguishable from the claimed invention.

Further, Applicants do not believe that the remaining cited art can be relied on solely even if combinable to remedy the deficiencies of Bachler. Nowhere does the remaining cited art disclose or suggest the gelled nutritional compositions as claimed, let alone methods of providing nutrition to a patient suffering from dysphagia or methods for providing supplemental nutrition to child that utilize gelled nutritional compositions as claimed. Indeed, the primary emphasis of Kadan relates to the exclusion of eggs from nutritional compositions, such as flan-type puddings. See, Kadan, Abstract. Moreover, Kadan provides that the resulting flans are complex multi-component products that exhibit an unpredictable texture (see, Kadan, col. 2, lines 30-40) in contrast to the gelled nutritional compositions, let alone in clear gel form as further defined in claim 37.

With respect to the Schneiderwirth reference, the primary emphasis relates to providing gels of water insoluble salts associated with alkaline earth metals that are colloiddally dispersed in an aqueous medium and which allegedly may be useful in supplying minerals and vitamins. See, Schneiderwirth, col. 1, lines 1-30. However, such a composition cannot be used as a complete

and well-balanced nourishment for persons in need of same. In contrast, the gelled nutritional compositions as claimed are particularly beneficial for dysphagia patients, children and the like and thus can be readily swallowed in addition to providing a well-balanced nutrition.

With respect to the Food Values reference, indeed, this reference merely provides a list of food constituents and their total energy content. At most, the gelatin desserts listed therein provide a relatively high carbohydrate content. However, this provides little if any additional support to Bachler as it merely illustrates what is generally known in the art that sweets have a high carbohydrate content.

What the Patent Office has done is to apply hindsight reasoning in support of the obviousness rejection. Of course, this is improper. Indeed, the Patent Office has relied on alleged teachings from four different references where the number of references on its own suggests an improper use of hindsight analysis in support of the obviousness rejection. Further, the primary Bachler reference is deficient with respect to a number of claim features as discussed above. Indeed, nowhere does Bachler provide or suggest the gelled nutritional compositions as claimed and their beneficial effects with respect to providing nutrition to a patient suffering from dysphagia or for providing supplemental nutrition to a child as further defined in claims 47 and 54, respectively. Moreover, clearly the remaining references are also deficient with respect to gelled nutritional composition as claimed and their advantages with respect to nutrition, such as for providing nutrition to a patient suffering from dysphagia. Indeed, the primary Bachler reference effectively teaches away from gelled nutritional compositions that provide a well-balanced nutrition for persons recovering from surgery and suffering from dysphagia and the like as claimed and previously discussed.

Applicants have surprisingly discovered a nutritional product with a gel consistency that is suitably adapted for administration to dysphagia patients and the like and that have a high nutritional value such that the product is composed of high amounts of carbohydrates, low amounts of fat, moderate amounts of proteins, vitamins and minerals. Moreover, the claimed gelled composition in form and color (i.e., clear gel form as required by claim 37) is different to what one skilled in the art would have expected from such type of composition. Indeed, multi-component food products are generally recognized as complex and unpredictable that result from unknown interactions associated with the ingredients therein, such as intermolecular hydrogen

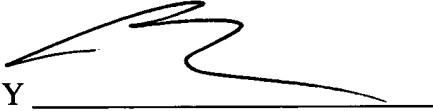
bonding, bonding via electrostatic forces, van der Waals forces or hydrophobic static forces, respectively. Again, nowhere does the cited art recognize the advantages of gelled nutritional compositions that can provide well-balanced nutrition as well as promote ready use of same, particularly with respect to the administration thereof to persons suffering from dysphagia and the like as claimed. Therefore, Applicants do not believe that one skilled in the art would be inclined to modify and/or combine the cited art to arrive at the claimed invention.

Based on at least these reasons, Applicants believe that the cited art fails to disclose or suggest the claimed invention. Therefore, Applicants respectfully submit that the cited art, even if combinable, fails to render obvious the claimed invention.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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